Office-Supreme Court, U.S.
FILED
AUG 4 1981
ALEXANDER L. STEVAS,
CLERK

No. 80-2067

# In the Supreme Court of the United States

OCTOBER TERM, 1980

JERRY J. COLAHAN, ET AL., PETITIONERS

*v.*

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT*

## BRIEF FOR THE UNITED STATES IN OPPOSITION

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## QUESTIONS PRESENTED

1. Whether the Food and Drug Administration reasonably could interpret Section 502(f) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(f), as authorizing it to declare some drugs "not safe for animal use except under the supervision of a licensed veterinarian" and to impose restrictions on the labeling, distribution and use of those veterinary drugs.

2. Whether the district court's order vacating a stipulated order which prohibited petitioners from dispensing certain veterinary drugs had the effect of dissolving a preliminary injunction and therefore was appealable under 28 U.S.C. 1292(a)(1).

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## BRIEF FOR THE UNITED STATES IN OPPOSITION

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A14-A21) is reported at 635 F.2d 564. The memorandum opinion and order of the district court filed October 9, 1979 (Pet. App. A1-A9) and the order of the district court filed February 12, 1980 (Pet. App. A10-A13) are unreported.

### JURISDICTION

The judgment of the court of appeals was entered on December 11, 1980, and a petition for rehearing was denied on March 5, 1981 (Pet. App. A22-A23). A petition for a writ of certiorari was filed on June 2, 1981.

The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTE AND REGULATIONS INVOLVED

Pertinent portions of Section 502 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352, and 21 C.F.R. 201.105 are reprinted at Pet. 2-4. In addition, 21 C.F.R. 201.5 provides in pertinent part:

> "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended.

21 C.F.R. 201.110 provides:

> A drug subject to § 201.105 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

## STATEMENT

1. Section 502(f) of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. 352(f), requires that drugs[1] bear "adequate directions for use," and drugs that fail to do so are deemed to be misbranded. The term "adequate directions for use" means use by laymen. 21 C.F.R. 201.5 A proviso to Section 502(f), however, authorizes the FDA to exempt drugs from this labeling requirement where it "is not necessary for the protection of the public health."

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[1] Section 201(g)(1) of the Act defines "drugs" to include both human and veterinary drugs. 21 U.S.C. 321(g)(1).

Since 1938, the FDA has recognized that some drugs cannot be used safely except under a veterinarian's supervision and these by definition cannot be labeled adequately for laymen's use. Such drugs nonetheless can be of great medical benefit when used under the direction of a licensed health professional. Thus, rather than totally ban the drugs as misbranded, the FDA has exempted them under the Section 502(f) proviso so long as they are sold pursuant to a veterinarian's prescription or other order. The agency's rationale is that "adequate directions for use" are not "necessary" because the veterinarian's directions protect the public health. The result of this policy is that many useful veterinary drugs are now available which otherwise would have to be withdrawn.[2]

The current regulations basically specify three relevant conditions for exemption. The drugs must be distributed by persons who are "regularly and lawfully engaged in" the handling of such drugs. 21 C.F.R. 201.105(a)(1). The drugs must be "sold only to or on the * * * order of" a licensed practitioner for use in his professional practice. *Ibid.* The drugs must bear, *inter alia*, a legend stating: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 21 C.F.R. 201.105(b)(1).

Veterinary drugs which can be used properly only under the supervision of a veterinarian but which do

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[2] Nearly half of the roughly 1200 veterinary drugs for which the agency has approved New Animal Drug Applications (see Section 512 of the Act, 21 U.S.C. 360b) are labeled for use only by or on the order of a veterinarian. Included are narcotics, barbiturates, anesthetics, anticonvulsants, hormones (including steroids), stimulants and tranquilizers.

not satisfy all three conditions for exemption are misbranded because they do not and cannot bear adequate directions for lay use.

2. On November 3, 1978, the United States filed this action in the United States District Court for the Northern District of Ohio, requesting an injunction against petitioners to stop them from receiving and selling "misbranded" drugs in violation of Section 301 of the Act, 21 U.S.C. 331.[3] The complaint alleged numerous instances in which petitioners, without a prescription or other order, sold drugs that require a veterinarian's directions for safe use.[4] The complaint also alleged that petitioners are not "regularly and lawfully engaged in" the distribution of drugs that are restricted to use under a veterinarian's directions. Since the drugs did not satisfy the conditions for exemption under 21 C.F.R. 201.105, they were misbranded.

On November 3, 1978, the district court issued a temporary restraining order that broadly prohibited petitioners from distributing misbranded drugs. Six days later, the court entered a stipulated order pursuant to which petitioners agreed not to distribute nine named drugs until further order of the court. On November 14, 1978, the court permitted the tem-

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[3] Section 301(a) of the Act, 21 U.S.C. 331(a), prohibits the introduction or delivery for introduction into interstate commerce of any misbranded drug. Section 301(k), 21 U.S.C. 331(k), prohibits the doing of any act to any drug while held for sale after shipment in interstate commerce which results in the article being misbranded.

[4] Steroids and other hormones were among the drugs which petitioners sold. Contrary to their claim (Pet. 9), the record in the trial court did not establish that all or some of the drugs sold by petitioners were available over-the-counter under different names.

porary restraining order to expire, but expressly continued the stipulated order pending a hearing on the government's request for a preliminary injunction. In January 1979, petitioners moved for dissolution or modification of the stipulated order on the ground that the FDA lacked statutory authority to promulgate 21 C.F.R. 201.105.

3. On October 9, 1979, the district court ruled that the FDA lacked authority to promulgate 21 C.F.R. 201.105 (Pet. App. A1-A9). It held that the plain meaning of the proviso to 21 U.S.C. 352(f) exempts only those drugs which are sufficiently safe that directions for use are unnecessary (Pet. App. A3-A4). The court reasoned that Congress never granted the FDA authority to deal with the situation where "adequate directions for use" could not be written (Pet. App. A4). Thus, notwithstanding the longevity or "logic" of the FDA regulation, the court concluded that it was beyond the statutory authority of the FDA to adopt (Pet. App. A8).[5] Accordingly, the court vacated the stipulated order, stating that "these defendants cannot be enjoined at this time" (Pet. App. A9). The government appealed pursuant to 28 U.S.C. 1292(a)(1).

4. The court of appeals reversed (Pet. App. A14-A21). It ruled that "the order vacating the stipulated order amounted to the dissolution or refusal of an injunction within the meaning of § 1292(a)(1)" (Pet. App. A16). On the merits, the court of appeals

[5] The court also rejected the FDA's argument that 21 C.F.R. 201.105 was authorized by Section 701(a), 21 U.S.C. 371(a), which permits the FDA "to promulgate regulations for the efficient enforcement of this Act * * *," and Section 512, 21 U.S.C. 360b, which authorizes restriction of animal drugs to use under veterinary supervision as part of the FDA's premarket approval process (Pet. App. A6-A9).

reasoned that the language of Section 502(f) is susceptible to more than one reasonable construction (Pet. App. A19). The court validated the FDA's interpretation, and concluded that petitioners' interpretation requiring the FDA either to allow the unrestricted sale of dangerous drugs or to forbid all sales of useful drugs was "a totally unreasonable result" (*ibid.*). Moreover, the court of appeals concluded that Congress had been aware of the FDA's longstanding interpretation and that Congress had amended the statute without altering the FDA's construction (Pet. App. A19-A20). Finally, the court of appeals recognized that the FDA's interpretation had been approved previously by two other courts of appeals (Pet. App. A21).

## ARGUMENT

The decision of the court of appeals is correct, does not conflict with any decision of this Court or any other court of appeals, and does not merit further review.

1. The court of appeals correctly held that the FDA has statutory authority to promulgate a regulation which exempts veterinary prescription drugs from the "adequate directions for use" requirement of the Act. Section 502(f)(1) declares all drugs to be misbranded unless their label bears "adequate directions for use." 21 U.S.C. 352(f)(1). The FDA, however, is empowered to exempt drugs from this requirement if directions are "not necessary for the protection of the public health." *Ibid.*

Since 1938 the FDA has interpreted this proviso in two ways. First, it has exempted drugs for which "adequate directions * * * are known by the ordinary individual." 3 Fed. Reg. 3168 (1938). Second, it has exempted drugs if, among other requirements, their label bore "the statement 'Caution: To be used

only by or on the prescription of a ————' (the blank to be filled in by the word 'Physician,' 'Dentist', or 'Veterinarian' * * *)." *Ibid.* In the latter situation the exemption from misbranding is justified because the veterinarian provides the directions required to protect the public health. The second interpretation may not be the most obvious one, but it is a reasonable construction of the statutory language, and thus a reviewing court is bound to respect it. See *Udall* v. *Tallman*, 380 U.S. 1, 16-17 (1965).

In addition, the regulation was promulgated contemporaneously with the adoption of the statute and it has remained essentially unaltered for more than 40 years.[6] These are powerful factors supporting its validity. See *United States* v. *Rutherford*, 442 U.S. 544, 553-554 (1979); *Power Reactor Development Co.* v. *International Union of Electrical, Radio & Machine Workers*, 367 U.S. 396, 408 (1961).

Finally, Congress amended the statute long after the regulations had been in effect, but expressly declined to overturn the interpretation adopted by the

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[6] Petitioners' unsupported assertion (Pet. 21) that the FDA did not require directions for "lay use" to apply to "veterinary drugs" until 1952 is simply mistaken. See *Alberty Food Products* v. *United States*, 194 F.2d 463, 464 (9th Cir. 1952); H.R. Rep. No. 700, 82d Cong., 1st Sess. 7 (1951). The 1938 regulations clearly apply to veterinary drugs and refer to "ordinary individuals." 3 Fed. Reg. 3168 (1938).

After Congress amended the Act in 1951 to modify the regulation of human prescription drugs (Act of Oct. 26, 1951, ch. 578, 65 Stat. 648), the FDA revised its regulations exempting drugs that require professional supervision and for many years treated human and animal drugs in the same regulation. 17 Fed. Reg. 6818-6819 (1952) (then codified as 21 C.F.R. 1.106 (1954)). In 1975 the agency recodified the veterinary drug regulations as 21 C.F.R. 201.105. None of these changes, however, altered the basic requirements originally adopted in 1938.

FDA. In 1951 Congress passed the Humphrey-Durham Amendments (Act of Oct. 26, 1951, ch. 578, 65 Stat. 648), to modify the regulation of human prescription drugs. Petitioners make much of the distinction that is drawn in those amendments between the treatment of drugs intended for humans and those for animals (Pet. 11-13). The legislative history, however, shows that Congress recognized the prior interpretation of Section 502(f)(1) relating to animals and approved it.

The clearest explanation of the effect of the amendments on veterinary drugs is in the Senate Report. It states:

> Under the Committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, *although it will be possible under section 502(f)* [21 U.S.C. 352(f)] *to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian.*

S. Rep. No. 946, 82d Cong., 1st Sess. 8 (1951) (emphasis added). Thus, Congress was aware of the prior FDA interpretation of 502(f) and chose to alter it, in part, for human drugs,[7] but to leave it

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[7] Contrary to petitioners' assertion (Pet. 12), the purpose of the 1951 Amendments was not to authorize the FDA to require prescription status for human drugs; the agency already had that authority under Section 502(f). Rather they were meant to define by statute the criteria under which human drugs would be deemed prescription or non-prescription. 21 U.S.C. 353(b)(1). S. Rep. No. 946, 82d Cong., 1st Sess. 3-4 (1951); 97 Cong. Rec. 9321, 9325 (1951).

Other purposes of the amendments were to define the term "prescription drug" (21 U.S.C. 353(b)(2)) and to relieve druggists from the risks of prosecution created by this Court's decision in *United States* v. *Sullivan*, 332 U.S. 689 (1948). See page 10, *infra*.

unchanged with regard to veterinary drugs. As one commentator on the Humphrey-Durham Amendments, cited by petitioners, explained:

> The regulations as they now stand and as published in the *Federal Register* of July 25, 1952, are, to all intents and purposes, practically the same with respect to drugs for animal use as they were before. The Act itself has not changed.

Collins, *Federal Drug Regulations as They Apply to Veterinarians*, 8 Food Drug Cosm. L. J. 333, 335 (1953).

Congress did not, as petitioners urge, exempt veterinary drugs from regulation, but instead simply declined to impose the full regulatory regimen of the Humphrey-Durham Amendments on those drugs. It left the prior interpretation of Section 502(f) intact.[8]

Obviously, knowing congressional acquiescence in an agency interpretation of its organic statute attests overwhelmingly to the validity of the agency's regulation. See *Board of Governors* v. *First Lincolnwood Corp.*, 439 U.S. 234, 248 (1978); *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 381 (1969). The court of appeals' decision upholding 21 C.F.R. 201.105 as within the FDA's statutory authority is plainly correct.[9]

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[8] Indeed, the exemptions from labeling provided by the amendments in 21 U.S.C. 353(b)(2) apply only from the time of dispensing by the pharmacist. Until then, even human prescription drugs continue to need exemption under the Section 502(f) proviso. *United States* v. *Articles of Drug*, 625 F.2d 665, 672 (5th Cir. 1980).

[9] Congress even more recently acknowledged and approved the FDA's interpretation of Section 502(f). The House Report on the Medical Device Amendments of 1976 states:

> This authority is derived from section 502(f) of the Act, which authorizes exemptions to the requirement

2. The decision of the court of appeals in no way conflicts with this Court's decision in *United States* v. *Sullivan*, 332 U.S. 689 (1948). Indeed, petitioners actually argue (Pet. 20) that the decision conflicts in principle only with the concurring opinion of Justice Rutledge. 332 U.S. at 703. Neither the opinion of the Court nor Justice Rutledge's concurring opinion casts any doubt upon the validity of the court of appeals' decision.

In *Sullivan*, a pharmacist transferred tablets from a properly labeled bottle to another bottle bearing only the name of the drug and then sold the second bottle to consumers. The Court held that the second bottle lacked "adequate directions for use" and held that application of the Act to Sullivan's situation was constitutional. 332 U.S. at 695-698. Obviously, those holdings are irrelevant to this case.

Justice Rutledge, in his concurring opinion, discussed Section 502(f), 21 U.S.C. 352(f), and referred to "the limited scope of the proviso, which directs

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that all devices bear adequate directions for use. The Food and Drug Administration's contention that such an exemption may be conditioned upon the use of a device only by or on the order of a licensed practitioner has been upheld by the courts.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 24-25 (1976).

Petitioners argue (Pet. 13) that recent legislation proposed by the FDA to clarify its authority over veterinary drugs, H.R. 7035, 96th Cong., 2d Sess. (1980), is an indication that the FDA now recognizes its limited authority in this area. That legislation, however, was proposed solely in response to the district court's decision in this case. Prior to that decision, the FDA never doubted its authority to adopt 21 C.F.R. 201.105. The FDA's request for this clarification is no indication that its prior interpretation was incorrect. See *American Trucking Associations* v. *Atchison, T. & S.F. Ry.*, 387 U.S. 397, 418 (1967).

the Administrator to make exemptions only when compliance with clause (1) 'is not necessary for the protection of the public health'." 332 U.S. at 702. The point of this reference, however, was to assure owners of corner grocery stores that misbranding under the decision of the Court did not apply to most classes of foods and thus they need not fear prosecution for mislabeled "candies." *Id.* at 703. Justice Rutledge in no way suggested that the proviso should be afforded a narrow interpretation where, as here, potentially dangerous drugs are involved.

3. The court of appeals' holding is consistent with the only other decisions of courts of appeals that have reviewed the FDA's interpretation of 21 U.S.C. 352(f). In *United States* v. *Articles of Drug*, 625 F.2d 665, 674 (5th Cir. 1980), the court recently held that "the agency's view is that they [prescription drugs] pose no threat to the public health prior to dispensing so long as they comply with the terms of the exemption in the regulation [21 C.F.R. 201.100, the human drug equivalent of 201.105]. This view is certainly a reasonable interpretation of the statute." See also *United States* v. *El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951). This uniformity of appellate court opinion makes review of this issue by this Court unnecessary.[10]

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[10] Petitioners also argue (Pet. 21) that the court of appeals wrongly decided "an issue which the District Court has not yet reached * * * whether by the mere affixation [by a manufacturer, presumably] to a label of an animal drug of a warning 'Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian,' it is *per se* impossible for 'adequate directions for use' to be written as required by § 502(f)." The court of appeals decided no such thing. The court, of course, upheld 21 C.F.R. 201.105, but that regulation requires a cautionary legend only if adequate directions for

4. Petitioners' second contention, that the court of appeals erred in allowing an appeal from the district court's order under 28 U.S.C. 1292(a)(1), is equally unworthy of review by this Court. The court of appeals correctly held that the district court's October 9, 1979, order had the effect of dissolving a preliminary injunction (Pet. App. A16). The district court dissolved a stipulated order which in turn had replaced a temporary restraining order.

This Court has recognized that a temporary restraining order that is extended beyond the 20-day limit in Fed. R. Civ. P. 65(b) can be treated for purposes of appeal as a preliminary injunction. See *Sampson* v. *Murray*, 415 U.S. 61, 86-87 (1974). Thus, the stipulated order should be treated as a preliminary injunction in this case. The district court's decision on the merits and over the United States' objection to dissolve the stipulated order created a right to immediate appeal. See *Gardner* v. *Westinghouse Broadcasting Co.*, 437 U.S. 478, 481 n.7 (1978).

Alternatively, the October 9, 1979, order could be viewed as a denial of the government's motion for a preliminary injunction (Pet. App. A16). The district court held that the government was unlikely to prevail on the merits and expressly stated that petitioners "cannot be enjoined at this time from the conduct complained of under the authority of § 201.105" (Pet. App. A9). This is a familiar ex-

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lay use cannot be written. It does not provide that the "mere affixation" of a cautionary legend means that adequate directions for lay use cannot be written. Indeed, where such directions are feasible, a manufacturer's voluntary use of the legend causes the drug to be misbranded under Section 502(a), 21 U.S.C. 352(a).

ercise of equity practice even if the precise words "preliminary injunction" were not used. Cf. *Ettelson* v. *Metropolitan Life Ins. Co.*, 317 U.S. 188, 192 (1942).[11] Therefore, an immediate appeal was appropriate.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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AUGUST 1981

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[11] The court of appeals' reversal and remand do no more than direct the district court to reinstate the stipulated order which it dissolved because of its erroneous view of the lawfulness of 21 C.F.R. 201.105. Contrary to petitioners' contention (Pet. 23-24) the court of appeals has neither permanently enjoined their distribution of the nine disputed drugs nor has it prevented petitioners from demonstrating that these drugs can be adequately labeled for lay use. In fact, the court directed the lower court to conduct further proceedings (Pet. App. A21).

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